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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,972

12/05/2005

Shawn DeFrees

40853-01-5083-US01

2406

43850

7590

10/21/2008

MORGAN, LEWIS & BOCKIUS LLP (SF)
One Market, Spear Street Tower, Suite 2800
San Francisco, CA 94105

EXAMINER

HEARD, THOMAS SWEENEY

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

10/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,972	Applicant(s) DEFREES ET AL.	
	Examiner THOMAS S. HEARD	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-18, 23-29 and 31-96 is/are pending in the application.
- 4a) Of the above claim(s) 39-62, 66, 67 and 69-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-18, 23-38, 63-65, 68 and 78-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :02/04/2008; 10/24/2007; 03/13/2006; 01/09/2006.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, now claims 12-18, 23-38, 63-65, 68, 78-96, in the reply filed on 6/9/2008 is acknowledged. The traversal is on the ground(s) that the newly amended claims to form Group I and Group II now share a special technical feature and should be rejoined. This is not found persuasive because the lack of unity was established at the time the restriction was made. Art was found on Claim 1 establishing that the invention was neither a special technical feature nor a contribution over the prior art. Applicants have canceled the claim to which lack of unity was broken. Unity of invention is determined at the time of restriction/election and once broken, remains as such. Additionally, regarding the method claims the MPEP states the following: Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (PCT Rule 6.4). The examiner should bear in mind that a claim may also contain a reference to another claim even if it is not a dependent claim as defined in PCT Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, "Apparatus for carrying out the process of Claim 1 ...," or "Process for the manufacture of the product of Claim 1 ..."). Similarly, a claim to one part referring to another cooperating part, for example, "plug for cooperation with the socket of Claim 1 ..." is not a dependent claim (see MPEP 1850).

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Therefore, the method claims are in a different category: method of using the products.

Therefore, these claims lack unity of invention.

Rejoinder of the method will be considered at the time allowable subject matter has been acknowledged. The requirement is still deemed proper and is therefore made FINAL.

Applicant's have elected:

EPO peptide

In case the Examiner should require a specific EPO peptide, Applicants elect the EPO peptide represented by SEQ ID NO: 73 (mature EPO) depicted in Figure 65 of the application.

Glycan and PEG

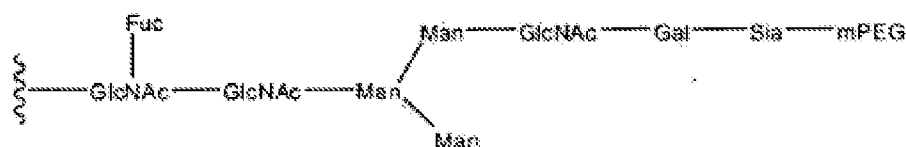
In case the Examiner should require a specific glycan, Applicants elect the glycan depicted in Figure 35A of the specification,

wherein

s, t and u are O;

r, i, a, e, j and v are I; and

R is methoxy poly(ethylene glycol) (m-PEG):



Claim(s) 12-18, 23-29, 31-96 are pending. Applicants have amended claim(s) 12, 14, 15, 17, 27, cancelled Claims 1-11, 19-22, and 30, and added Claims 78-96. Claims 39-62, 66, 67, 69, 70-77 are withdrawn. Claims 12-18, 23-38, 63-65, 68, 78-96 are hereby examined on the merits. Applicant's elected species has not been found to be free of the prior art as the species has been rejected under Obviousness Type Double Patenting.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 64 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright, EP 0605963 A2. The instant claimed invention is drawn to a glycoPEGylated EPO peptide, said EPO peptide comprising the sequence of SEQ ID NO:73 which is the native EPO peptide sequence, and the said sequence optionally comprising a mutation, in said sequence.

Wright discloses EPO pegylation through glycosyl residues that are naturally found in the EPO sequence, readable on SEQ IS NO:73 instantly claimed; see Claims 17 or Table II on page 22, for the EPO peptides that were pegylated via carbohydrate modifications. Further, on page 4, it is stated that one or more of the water soluble reagents may be coupled to individual polypeptides or similar organic molecules, to which would read on a mutant polypeptide of EPO, since only EPO is envisioned in the invention of EP 0605963 A2. Therefore, the invention is anticipated as claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-18, 23-38, 63-65, 68, 78-96 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-20, 26, 27, 31-34 of Defrees, et al, U.S. Patent No. 7,405,198. Although the conflicting claims are not identical, they are not patentably distinct from each other because the elected species of EPO with the same glycan structure is taught, as well as a plurality of other PEGylated EPO peptides are encompassed in the Markush of U.S. Patent No. 7,405,198.

The instant invention is drawn to a plurality of glycosylated EPO peptides that are pegylated through the glycosyl residues on the EPO. The EPO peptides are glycosylated through N-linked and O-linked glycans that are produced by the cells lines that make the glycosylated EPO peptides. To the isolated EPO peptide, the glycosyl residues may be removed or added as desired, and then PEGylated through the remaining glycan.

DeFrees, et al, U.S. Patent No. 7,405,198, teaches the elected EPO peptide with a plurality of glycan structure, see Claim 9, and 28, which is pegylated with a variety of PEGs. DeFrees et al further teaches a plurality of other peptides that encompass the embodiments of the instantly claimed invention. It would have been obvious at the time of the instant invention to continue the variation in the glycan structure as taught by Defrees et al, and arrive at the instantly claimed invention. One would have been motivated to do so given Defrees clear teaching of the Markush that embraces the compositions instantly claimed. Thus, the practice of one would be the practice of the because of the overlapping scope of the composition claimed.

Claims 12-18, 23-38, 63-65, 68, 78-96 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-29 of Defrees, et al, U.S. Patent No. 7,138,371. Although the conflicting claims are not identical, they are not patentably distinct from each other because the elected species of EPO with the same glycan structure is taught, as well as a plurality of other PEGylated EPO peptides are encompassed in the Markush of U.S. Patent No. 7,138,371.

Claims 12-18, 23-38, 63-65, 68, 78-96 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 40-44, 48-52 of Defrees, et al, 11/440,839. Although the conflicting claims are not identical, they are not patentably distinct from each other because a pegylated EPO with the same glycan

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structures are taught, as well as a plurality of other PEGylated EPO peptides that are encompassed in the Markush of 11/440,839.

Claims 12-18, 23-38, 63-65, 68, 78-96 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 4-18, 26-38, 46, 50, 52-81 of Defrees, et al, 11/144,233. Although the conflicting claims are not identical, they are not patentably distinct from each other because pegylated EPO with the same glycan structures are taught, as well as a plurality of other PEGylated EPO peptides that are encompassed in the Markush of 11/144,233.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Prior art contained in the reference of record can be applied in the next office action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas S Heard/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654